



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,271	10/07/2003	Kenneth G. Powell	7767-192152	3133
26253	7590	11/24/2004	EXAMINER	
DAVID W. HIGHTET, VP AND CHIEF IP COUNSEL BECTON, DICKINSON AND COMPANY 1 BECTON DRIVE, MC 110 FRANKLIN LAKES, NJ 07417-1880			DURAND, PAUL R	
			ART UNIT	PAPER NUMBER
			3721	

DATE MAILED: 11/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/679,271

Applicant(s)

POWELL ET AL.

Examiner

Paul Durand

Art Unit

3721

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 04/2004.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Art Unit: 3721

### **DETAILED ACTION**

1. Applicant's election with traverse of invention I, claims 1-26 in the reply filed on 8/20/2004 is acknowledged. Applicant has not provided an argument to support the traversal.

The requirement is still deemed proper and is therefore made FINAL.

Claim 27 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8/20/2004.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 24 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite the limitation "hollow conical structure" in the claims. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3721

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 1-6,8-12, and 15-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiler et al (US 4,176,153) in view of Oyler (US 4,924,919).

In regard to claims 1,3,8 and 12, Weiler discloses the invention substantially as claimed including retaining and positioning a container formed from sheets 22 and 29, expanding the container to a non relaxed state, placing fluid into the container in a pressure range, filling the container with fluid 34, sealing the container with formed member 35 and releasing the container (see Figs. 1-5 and C3,L52 – C4,L36). What Weiler does not disclose is the increase of pressure to environment and a vapor pressure range. However, Oyler teaches that it is old and well known in the art of packaging to provide a package 18, which is expanded by creating a reduced pressure environment, which is the subsequently filled and the pressure increased to atmosphere for the purpose of placing an object into a small opening (see Figs.1-6 and C2,L49 – C3,L29). Furthermore, while the modified invention of Weiler does not specifically disclose a vapor pressure range, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have selected a vapor pressure range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the

Art Unit: 3721

invention of Weiler with the reduced pressure means as taught by Oyler for the purpose of placing an object into a small opening.

In regard to claim 2, Weiler discloses the invention substantially as claimed including packaging in an aseptic environment (see C1,L18-26).

In regard to claim 4, the modified invention of Weiler discloses the invention substantially as claimed except for processing some of the steps in a simultaneous manner. However, the examiner takes Official Notice that it is well known in the art to perform packaging steps in a simultaneous manner for the purpose of increasing manufacturing throughput. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the modified invention of Weiler with simultaneous packaging steps for the purpose of increasing manufacturing throughput.

In regard to claims 5 and 6, the modified invention of Weiler discloses the invention substantially as claimed injecting a gas into an interior volume to expand the package (see Figs.1-6 and C2,L49 – C3,L29).

In regard to claims 9 and 10, the modified invention of Weiler discloses the invention substantially as claimed including physically expanding a package mechanically through the use of mandrel carriage 21 (see Figs. 1-6).

In regard to claim 11, the modified invention of Weiler discloses the invention substantially as claimed except for the forming and filling of packages at different locations. However, the examiner takes Official Notice that it old and well known in the art to manufacture a package at one location and then fill and seal the package at a

Art Unit: 3721

different location for the purpose of increasing manufacturing flexibility. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the modified invention of Weiler with means to manufacture a package at one location and then fill and seal the package at a different location for the purpose of increasing manufacturing flexibility.

In regard to claims 15 and 16, Weiler discloses the invention substantially as claimed except for a third volume which is less than the non-relaxed state volume. However, Oyler teaches that it is old and well known in the art to provide a package in a relaxed state, bring it to a non-relaxed state, fill the package and then reduce the pressure to bring the package to a volume that is less than the expanded volume for the purpose of placing an object inside a flexible package (see Figs. 1-8). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the invention of Weiler with the packaging means as taught by Oyler for the purpose of placing an object inside a flexible package.

In regard to claims 17-19, the modified invention of Weiler discloses the invention substantially as claimed except for the physical material properties of the package. However, it would have been an obvious matter of design choice to provide a package comprised of a hydrophilic, hydrophobic or a wettable surface, since applicant has not disclosed that a package comprised of a hydrophilic, hydrophobic or a wettable surface solves any stated problem or is for any particular purpose and it appears the invention would do equally well with the polymer surface as disclosed by Weiler.

Art Unit: 3721

In regard to claim 20, the modified invention of Weiler discloses the invention substantially as claimed including a package comprised of plural flexible components in the form of sheets 29 and 22 (see Fig. 1)

In regard to claims 21 and 22, the modified invention of Weiler discloses the invention substantially as claimed except for the flexible component comprising less or more than  $2/3$  of the package. However, it would have been an obvious matter of design choice to provide a package comprised of a flexible component comprising less or more than  $2/3$  of the package, since applicant has not disclosed that a package comprised flexible component comprising less or more than  $2/3$  of the package solves any stated problem or is for any particular purpose and it appears the invention would do equally well with the flexible component covering the full package as disclosed by Weiler.

6. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weiler et al and Oyler in view of Shaw (US 3,382,642).

The modified invention of Weiler discloses the invention substantially as claimed as applied to claim 1 above except for the use of an inert gas during the packaging process. However, Shaw teaches that it is old and well known in the art of packaging to use an inert gas during packaging for the purpose of increasing the shelf life of a product (see C6,L28-32). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the modified invention of Weiler with the packaging means as taught by Shaw for the purpose of increasing the shelf life of a product.

Art Unit: 3721

7. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiler et al and Oyler in view of Bullock et al (US 5,170,609).

The modified invention of Weiler discloses the invention substantially as claimed as applied to claim 1 above except for the expulsion of excess air from the package. However, Bullock teaches that it is old and well known in the art of packaging, to manipulate the contents of a package by compressing or contracting a flexible bag for the purpose of reducing the volume of air inside (see Figs. 1,2 and C4,L16-32). Furthermore, while Bullock does not disclose a manipulation of the meniscus, the examiner asserts that the manipulation of the package of Bullock moves the articles at the top of the product and is therefore equivalent in the art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the modified invention of Weiler with the packaging means as taught by Bullock for the purpose of reducing the volume of air inside.

8. Claims 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiler et al and Oyler in view of Green et al (US 5,673,731).

In regard to claims 23 and 26, the modified invention of Weiler discloses the invention substantially as claimed as applied to claim 1 above except for a conical opening. However, Green teaches that it is old and well known in the art of packaging to provide a contiguous conical fluid opening 38, with the narrowest point to the inside of container 12 for the purpose of accommodating a fill fitting (see Fig. 3). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention

Art Unit: 3721

was made to have provided the modified invention of Weiler with the fill means as taught by Green for the purpose of accommodating a fill fitting.

In regard to claims 24 and 25, the modified invention of Weiler discloses the invention substantially as claimed except for the conical fill opening being removable or non-removable. However, it would have been an obvious matter of design choice to provide a fill opening which is capable of being removable or non-removable, since applicant has not disclosed that a fill opening which is capable of being removable or non-removable solves any stated problem or is for any particular purpose and it appears the invention would do equally well with the flexible component covering the full package as disclosed by Weiler.

### ***Conclusion***


9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Durand whose telephone number is 571-272-4459. The examiner can normally be reached on 0730-1800, Monday - Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi I Rada can be reached on 571-272-4467. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3721

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Durand  
November 15, 2004

  
EUGENE KIM  
PRIMARY EXAMINER